



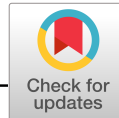
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## ORIGINAL ARTICLE

WILEY

# Effectiveness of submandibular duct relocation in 91 children with excessive drooling: A prospective cohort study

Saskia E. Kok<sup>1</sup> | Corrie E. Erasmus<sup>2</sup> | Arthur R. T. Scheffer<sup>1</sup> | Karen van Hulst<sup>3</sup> | Maroeska M. Rovers<sup>4</sup> | Frank J. A. van den Hoogen<sup>1</sup>

<sup>1</sup>Department of Otolaryngology-Head and Neck Surgery, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

<sup>2</sup>Department of Pediatric Neurology, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

<sup>3</sup>Department of Rehabilitation, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

<sup>4</sup>Department of Epidemiology, Biostatistics and HTA, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

## Correspondence

Saskia Kok, Department of Otolaryngology-Head and Neck Surgery, Radboud University Nijmegen Medical Centre, Postbox 9101, 6500HB Nijmegen, The Netherlands.  
Email: saskia.kok@radboudumc.nl

**Objective:** To evaluate the effectiveness of submandibular duct relocation (SMDR) in drooling children with neurological disorders.

**Design:** Prospective cohort study.

**Setting:** Academic Outpatient Saliva Control Clinic.

**Participants:** Ninety-one children suffering from moderate to severe drooling.

**Main outcome measures:** Direct observational drooling quotient (DQ; 0-100) and caretaker Visual Analogue Scale (VAS; 0-100). Secondary outcome measures were drooling severity (DS) and frequency rating scales.

**Results:** The DQ at baseline, 8 and 32 weeks postoperatively was 26.4, 12.3 and 10.8, respectively. VAS score decreased from 80.1 at baseline to 28.3 and 37.0 at 8 and 32 weeks after surgery. Median DS at baseline, 8 and 32 weeks was 5, 3 and 4, whereas the drooling frequency median scores were 4, 2 and 2, respectively. Five children required prolonged intubation due to transient floor of the mouth swelling, two of whom developed a ventilator-associated pneumonia. Another child developed atelectasis with postoperative pneumonia. Two more children needed tube feeding because of postoperative eating difficulties for 3 days or suprapubic catheterisation for urinary retention. Children aged 12 years or older (OR = 3.41;  $P = 0.03$ ) and those with adequate stability and position of the head (OR = 2.84;  $P = 0.09$ ) appeared to benefit most from treatment.

**Conclusions:** Submandibular duct relocation combined with excision of the sublingual glands appears to be relatively safe and effective in diminishing visible drooling in children with neurological disorders, particularly in children aged 12 years and older and those without a forward head posture.

## 1 | INTRODUCTION

Drooling is generally caused by an inability to swallow saliva effectively rather than by an excessive production of saliva.<sup>1,2</sup> Excessive drooling is considered to be abnormal in children older than age four. It is common among neurologically disabled children, and up to 60% of children with cerebral palsy have complaints of drooling.<sup>3-5</sup> It can lead to multiple personal and social consequences, such as difficulties in making friends and exclusion by peers; in severe cases, it may lead

to social isolation. Medical complications include a higher risk of skin infections, choking, aspiration, pneumonia and feeding or speech problems. Excessive drooling may also interfere with the child's daily care and rehabilitation therapies, creating an additional burden.<sup>6</sup>

A vast array of different therapies has been used to treat children with excessive drooling. These options include behavioural and non-medical interventions, anticholinergic medications, botulinum toxin injection into the salivary glands and surgery.<sup>7</sup> Evidence for the effectiveness of these treatments in drooling children is scarce and

(inter)nationally accepted guidelines are lacking. So far, various surgical approaches have been implemented.<sup>8</sup> In our centre we have established a multidisciplinary approach for drooling children. The most commonly applied surgical procedure in our centre is bilateral submandibular duct relocation (SMDR). By relocating the papillae of the submandibular ducts from the anterior oral cavity to the base of the tongue, saliva from the submandibular glands is able to flow directly into the oropharynx and triggers the pharyngeal swallow reflex immediately. Simultaneous excision of the sublingual glands reduces the risk of ranula formation.<sup>9</sup> In children with an impaired pharyngeal phase of swallowing SMDR is considered contraindicated because of the risk of aspiration.

Earlier studies suggest that SMDR is effective and safe.<sup>9-12</sup> Most studies performed so far, however, were small retrospective case series, that used subjective instead of objective outcomes. Furthermore, these studies showed that SMDR was not effective in all children. For more clarity, we formed this prospective cohort to study the effectiveness of SMDR, and tried to identify children that benefit more or less from this procedure.

## 2 | METHODS

### 2.1 | Ethical considerations

The present study was conducted in accordance with national and international ethical standards. Informed consent was obtained before each surgery by parents or caregivers.

### 2.2 | Patients

We performed a cohort study between March 2005 and December 2014. All 91 children and adolescents with excessive drooling who underwent SMDR were evaluated by our multidisciplinary team at the Radboud University Medical Centre, consisting of a speech and language therapist, otolaryngologist and a pediatric neurologist. All patients had a diagnosis of cerebral palsy or another non-progressive developmental disability. All participants were between 6 and 24 years of age at the time of enrolment, were considered to have a safe pharyngeal phase of swallowing and had at least moderate drooling, intermittent throughout the day. Fifty-six patients were treated with Botulin toxin injections prior to surgery. None of the participants had undergone previous surgical procedures for saliva control and no additional anticholinergic medication or Botulinum toxin injections were allowed during this study.

### 2.3 | Procedure

Surgery was performed under general anaesthesia. After the papillae of the submandibular ducts were located, the floor of the mouth was infiltrated with Prilocaine and Adrenaline, and an incision was made to create two mucosal islands containing the papilla. The submandibular duct was freed anterior to posterior, taking special care to prevent damage to the lingual nerve. The sublingual glands were resected

### Keypoints

- The first study to investigate submandibular BoNT-A injections as predictor of SMDR outcome in drooling.
- Submandibular BoNT-A injection effect does not predict SMDR outcome.
- Submandibular duct relocation is more effective and more permanent than BoNT-A injection

bilaterally to prevent ranula formation. After submucosal re-routing of the submandibular ducts to the oropharynx, the papillae were sutured at the base of the tongue with a single stitch, posterior to the glossopharyngeal plica. Children were given a single dose of corticosteroids during surgery and, if necessary, a second dose on the first postoperative day. We routinely prescribed a 7-day postoperative course of antibiotics (co-amoxiclav) with a 5-day period of diclofenac for pain management.<sup>13</sup> All children were admitted to an intensive care unit for 24 hours after surgery and stayed intubated to prevent airway obstruction problems in case of swelling of the floor of the mouth.

### 2.4 | Outcome measures

Primary outcome measures in this study were the drooling quotient (DQ) and a Visual Analogue Scale (VAS) score.

The DQ is a validated, direct-observational semi-quantitative objective method to assess the severity of drooling.<sup>14</sup> It is defined as the percentage of time a person drools and was measured by specially trained speech and language therapists. During two 5-minute sessions (one while the participants were concentrating and one while they were distracted) the absence or presence of new saliva on lip or chin was recorded every 15 seconds.<sup>15</sup> Participants were evaluated standardised at least 1 hour after a meal while awake and sitting erect. A caretaker VAS score, indicating the subjective drooling severity (DS) over the previous 2 weeks, was marked on a 10 cm-line, with 100 corresponding to severe drooling and zero to no drooling. A clinically relevant response to treatment was defined as  $\geq 50\%$  reduction in DQ or a reduction of  $\geq 2$  SDs in VAS score.<sup>16,17</sup> Secondary subjective outcome measures were drooling frequency (never, mild, moderate, severe, profuse; DF) and drooling severity (no, occasionally, frequently, constant; DS) for which we used the DF and DS rating scales introduced by Thomas-Stonell and Greenberg.<sup>18</sup>

### 2.5 | Statistical analysis

To study the effectiveness of SMDR we compared the DQ, VAS, DF and DS scores at baseline with the scores after 8 and 32 weeks using either a paired sample *t* test or a Wilcoxon rank. We performed logistic regression analyses to study which factors are associated with a better treatment outcome, which was defined as at least a 50% reduction in DQ 32 weeks after treatment. We calculated

odds ratios and their 95% confidence intervals. Factors univariable associated with outcome ( $P$ -value was set at  $<0.10$  at which a relationship to outcome could be considered as biologically plausible) were included in a multivariable logistic regression analysis. To reduce bias and to increase statistical efficiency, we imputed the missing data using the linear regression multiple imputation method available in SPSS. All statistical analyses were performed using SPSS 20.0 for Windows (SPSS Inc, Chicago, IL, USA).

### 3 | RESULTS

Between March 2005 and December 2014 91 children and adolescents underwent SMDR in our centre. Of the 91 included children,

**TABLE 1** Demographic data

	No. patients (valid %) N = 91
Gender	
Male	61 (67.0)
Female	30 (33.0)
Age	
<12 y	21 (23.1)
≥12 y	70 (76.9)
Mean (range)	15.0 (6-24)
Diagnosis	
Cerebral palsy <sup>a</sup>	
Bilateral paresis	60 (65.9)
Unilateral paresis	4 (4.4)
Other neurodevelopmental disabilities	27 (29.7)
GMFCS level (N = 64)	
I	3 (4.7)
II	8 (12.5)
III	19 (29.7)
IV	21 (32.8)
V	13 (20.3)
Epilepsy	
Controlled	41 (45.1)
Intractable	15 (16.5)
No epilepsy	35 (38.5)
Developmental age	
<4 y	47 (51.6)
4-6 y, IQ < 70	17 (18.7)
4-6 y, IQ > 70	3 (3.3)
>6 y	17 (18.7)
Unknown	7 (7.7)

GMFCS, Gross Motor Function Classification System, only applicable for children with cerebral palsy; I, able to walk; IQ, intelligence quotient; V, impaired in all areas of motor function.

<sup>a</sup>Confirmed by a paediatric neurologist.

61 were boys and 30 were girls. The mean age at surgery was 15 years (SD 4 years; range 6-24 years). Most children were diagnosed with cerebral palsy (70.3%). About half of the children with CP had a Gross Motor Function Classification System score of 4 or higher, which meant they were wheelchair-bound. Table 1 shows the baseline demographic characteristics.

#### 3.1 | Primary outcome measures

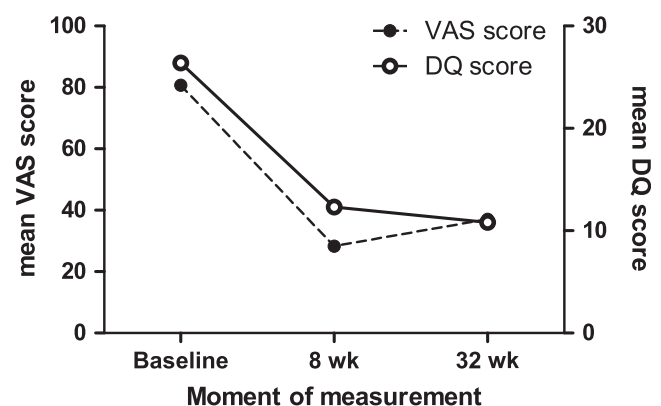
At baseline the mean DQ was 26.4 (95% CI 24.7-28.1). After 8 and 32 weeks, it was 12.3 (95% CI 11.1-13.5), and 10.8 (95% CI 9.4-12.1), respectively. See also Figure 1. Thirty-nine of the total of 273 DQ scores were missing (14.3%). Sixty children (66.0%) experienced a 50% reduction in DQ score at 32 weeks and were regarded as responders.

At baseline, 8 and 32 weeks the mean VAS scores were 80.7 (95% CI 79.6-81.8), 28.3 (95% CI 26.3-30.3) and 37.0 (95% CI 34.5-39.4), respectively. Twenty-nine of the total of 273 VAS scores were missing (10.6%). Sixty-seven children (73.6%) had a reduction of 2 SD in VAS score at 32 weeks.

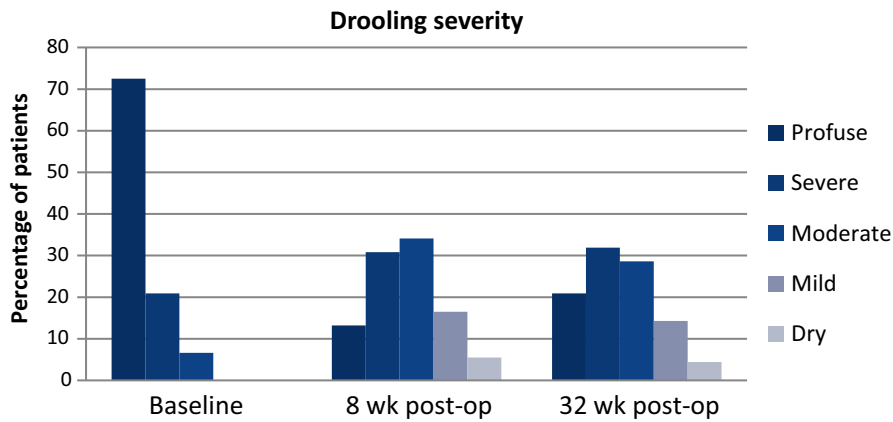
#### 3.2 | Secondary outcome measures

Figure 2 shows the distribution of DS scores at baseline, 8 and 32 weeks after surgery. Wilcoxon rank tests showed a significant decrease between baseline and 8 weeks as well as between baseline and 32 weeks after surgery ( $P < 0.001$ ). At baseline and 32 weeks after surgery 72.5% and 20.9%, respectively, had profuse drooling; at 32 weeks the majority of patients experienced moderate (28.6%) or severe drooling (31.9%). Thirty-one of the total of 273 DS scores were missing (11.4%).

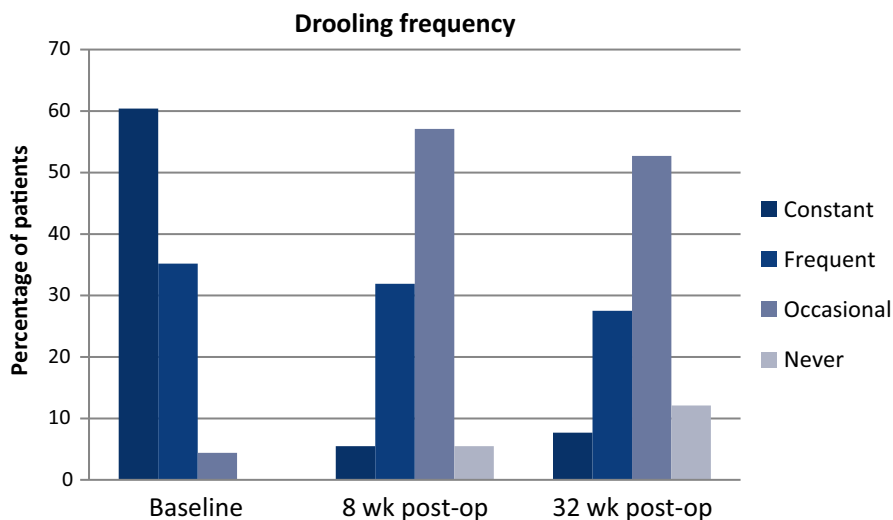
Figure 3 shows the distribution of DF scores. The baseline median DF score declined from 60.4% constant drooling at baseline to 7.7% after 32 weeks, at which time the majority of the participants only drools occasionally (52.7%). Thirty-two of the total of 273 DF scores were missing (11.7%).



**FIGURE 1** Subjective Visual Analog Scale (VAS) scores and drooling quotient (DQ), mean in time (N = 91)



**FIGURE 2** Drooling severity, marked by caregivers before and after surgery (N = 91)<sup>18</sup>



**FIGURE 3** Drooling frequency, marked by caregivers before and after surgery (N = 91)<sup>18</sup>

### 3.3 | Subgroups

A 50% reduction in DQ was considered a clinically relevant improvement. At 32 weeks 60 children (66.0%) experienced a 50% reduction in DQ score. Three patients (3.3%) had a DQ of zero both pre and postoperatively; they were considered as non-responders in the statistical analysis, even though two of them expressed satisfaction with the procedure. By analogy with Erasmus et al<sup>19</sup>, in this study 11 patient characteristics (Table 2) were considered to be possible variables associated with treatment response based on biological plausibility. They were analysed by logistic regression. Univariable logistic regression analysis showed that children with adequate head stability and those aged 12 years or older benefited the most from surgery ( $P < 0.10$ ). Multivariable logistic regression with these two factors supported these results, with a significantly better outcome for children above 12 years of age (OR = 3.41;  $P = 0.03$ ) and a trend towards children without anterior flexion of the head (OR = 2.84,  $P = 0.09$ ). Table 3 shows the distribution of success rates among patients according to age and/or head stability. Success rates are highest in children older than 12 years with an adequate head stability (78%). Success rates are lowest in children younger than 12 years without adequate head stability (18%), this group only includes 11 children.

### 3.4 | Adverse events

The mean surgical time was 93 minutes, with a mean duration of hospital stay of 4.40 days (range 2-11). Five children experienced transient swelling of the floor of the mouth, which required prolonged intubation; two of them developed ventilator-associated pneumonia. One child had postoperative eating difficulties and received tube feeding for 3 days. One child developed an atelectasis and postoperative pneumonia. One child experienced urinary retention postoperatively, which required suprapubic catheterisation. None of the children suffered from ranulas.

## 4 | DISCUSSION

### 4.1 | Synopsis of key/new findings

Our results show that bilateral SMDR with excision of the sublingual glands appears to be an effective treatment for drooling. Objective and subjective measurements improved significantly after surgery. The majority of patients improve from frequent or constant drooling to occasional drooling, and they drool less severely. Children aged 12 years or older and those with an adequate head stability appeared to benefit most from this treatment.

**TABLE 2** Variables negatively contributing to treatment response

Clinical characteristic	Univariable analyses		Multivariable analyses	
	OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Male	1.57 (0.35-7.08)	0.54	–	–
Age <12 y	3.67 (1.28-10.55)	0.02	3.41 (1.12-10.38)	0.03
Cerebral palsy	1.19 (0.45-3.15)	0.73	–	–
GMFCS level IV-V	0.78 (0.25-2.42)	0.67	–	–
Epilepsy	1.28 (0.43-3.79)	0.65	–	–
Developmental age				
<4 y or 4-6 y, IQ < 70	1.43 (0.46-4.44)	0.54	–	–
BTX therapy previously	0.45 (0.16-1.26)	0.13	–	–
Ante flexion head position	3.03 (0.93-9.84)	0.06	2.84 (0.84-9.63)	0.09
Abnormal lip closure	0.62 (0.24-1.58)	0.32	–	–
Tongue protrusion	0.70 (0.22-2.20)	0.53	–	–
Abnormal tongue movements	1.59 (0.41-6.11)	0.49	–	–

BTX, botulinum toxin; CI, confidence interval; GMFCS, Gross Motor Function Classification System; IQ, intelligence quotient; OR, odds ratio. All variables were dichotomous (0 or 1). P value  $\leq 0.05$  indicates statistical significance.

**TABLE 3** Distribution of success rates according to age and/or head stability

Characteristic	Baseline (N)	Responder (N)	Non-responder (N)	Success rates DQ 32 wk, %
Age				
<12 y	21	9	12	42.9
$\geq 12$ y	70	51	19	72.9
Head position				
Inadequate head stability (IHS)	40	21	19	52.5
Adequate head stability (AHS)	51	39	12	76.5
Combination				
<12 y + IHS	11	2	9	18.2
$\geq 12$ y + IHS	29	39	10	65.5
<12 y + AHS	10	7	3	70.0
$\geq 12$ y + AHS	41	32	9	78.0

DQ, drooling quotient.

## 4.2 | Strengths and limitations of the study

Strengths of our study include the analysis of prospectively collected data of both subjective and objective measurements to evaluate the effect of this procedure. With pre and postoperative assessments, we could evaluate change over time. In addition, we identified subgroups, which could benefit most from this intervention. Using multiple imputation we established the best way to deal with missing values. Some potential limitations should also be mentioned. First, we used no control group as this is a cohort study and the range of ages is also quite wide in our study. Second, data in the present study were collected in one clinic in one country. Despite this we expect that results might be generalisable because the patients' characteristics and a surgical procedure are comparable to others.

## 4.3 | Comparisons with other studies

The results of the present study are in agreement with previous research.<sup>9-11</sup> Former studies have predominantly focused on subjective postoperative satisfaction, often without preoperative assessment. To date Crysdale et al<sup>20</sup> evaluated the largest group (n = 106) with data on patient satisfaction. In that study, preoperative drooling VAS score of 8.1 (on a scale to 10) had decreased to 4.9 after a mean follow-up of 4 years. Although subjective measurements are an important evaluation tool objective measurements are necessary to evaluate interventions properly. There are some studies on surgery that use objective methods. Ekedahl et al<sup>21</sup> measured a significant decrease in drooling by intravenously administered radioactive isotopes. Webb et al<sup>22</sup> used the DQ in 28 patients and in his study the measured DQ of 50.0 at baseline decreased after surgery to 12.3. With our present study we show a significant decrease in the severity of drooling postoperatively in objective as well as subjective measurements.

## 4.4 | Clinical applicability of the study

This study demonstrated a possibly favourable outcome in children with adequate head stability. Contrary to other surgical procedures such as extirpation of the submandibular glands, the amount of produced saliva is not markedly reduced after SMDR. It is therefore possible that in children with poor posture control and incomplete lip closure, saliva can still re-enter the oral cavity and cause drooling.<sup>23</sup> In such cases submandibular gland excision is possibly more effective than SMDR.

In this study children older than 12 years benefit more from SMDR. We have no adequate explanation for this. It could be because of further development of oral cavity function and/or head stability. There could also have been a selection bias in which children with worse drooling visited our outpatient clinic earlier and received earlier surgery. The age at which this procedure is performed in these children varies throughout literature. There are centres where this procedure is performed from 4 or 5 years of age.<sup>9-12,24,25</sup> Based on our results, assuming saliva control will improve with ongoing development and the risks that are involved in this surgery, in general we recommend SMDR after the age of 12 years.

Extensive floor of the mouth surgery, as in SMDR, might lead to extensive swelling of the floor of the mouth or tongue. The resulting airway obstruction may necessitate intubation that can be very difficult and challenging in a distressed and neurological disabled child. In our study five children experienced swelling of the floor of the mouth which required prolonged intubation. To avoid this risk we prefer and advise to keep these children intubated for 12-24 hours after surgery. Before extubation an inspection of the tongue and floor of the mouth should be performed.

Submandibular duct relocation is the most commonly performed surgical procedure to treat anterior, visible drooling in our centre in children with adequate pharyngeal swallow function. There are no external scars and saliva production is mostly preserved. In young children botulinum toxin treatment could bridge the time until a child is old enough to endure surgery. This has been previously suggested.<sup>13</sup> Botulinum toxin injections are less invasive, no hospitalisation is needed and they are effective in approximately 50% of the patients.<sup>17</sup> However, their effect is generally temporary and it could require repeated general anaesthesia. Therefore, in older children more definitive solution is favourable. In case of saliva aspiration or when the pharyngeal phase of swallowing is likely to worsen over time due to the underlying cause, SMDR is contra-indicated. In these cases we recommend a treatment which reduces the amount of saliva produced instead of relocating the saliva to lower the risk of aspiration.

In conclusion, our study supports that SMDR is a safe and effective method to reduce visible drooling without saliva aspiration in neurological disabled children. An age under 12 years and decreased head stability negatively influence outcome of surgery. We recommend considering other treatment options, in case of age <12 years botulinum toxin injections could bridge to an older age and in obvious head instability surgical treatments like submandibular extirpation or ligation of the submandibular ducts could be used.

## ACKNOWLEDGEMENTS

None.

## CONFLICT OF INTEREST

None declared.

## ORCID

Saskia E. Kok  <http://orcid.org/0000-0003-4773-5461>

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